REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

This amendment adds, changes and/or deletes claims in this application. A detailed listing is presented, with an appropriate defined status identifier, of all claims that are or were in the application, irrespective of whether the claim(s) remain under examination.

In particular, claims 113 and 114 are added and claims 41, 56, 92, and 108 are canceled, without prejudice or disclaimer. Support for the new claims can be found throughout the specification as-filed, including the original claims.

No new matter is implicated by these changes. After entry of the present paper, moreover, claims 29-32, 34-40, 42-47, 49-55, 57-61, 63-91, 93-107, and 109-114 will be pending.

II. Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claims 29-32, 34-47, 49-61 and 63-1 12 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. According to the Office Action, "while being enabling for transfecting APCs with DNA encoding an antigen distributed on a particle surface using a gene gun by intradermal or subcutaneous injection, transfecting APCs of the skin and obtaining an immune response against the antigen, does not reasonably provide enablement for eliciting an immune response that destroys HIV infected cells using DNA encoding gp120 or gp160 as encompassed by the claims." Office Action at 2. Applicants respectfully traverse this ground of rejection.

A. The Claimed Invention Is Enabled

The specification provides ample guidance to make and use the claimed invention without undue experimentation. Indeed, the specification describes how to make and use the claimed invention and has working examples to support the disclosure. These working examples demonstrate the operability of the claimed invention using a tumor model. *See* Examples on pages 25 and 29. There is no reason to doubt that these same methods could also be used effectively to generate an anti-viral response. Indeed, APC-mediated immune responses that are dependent on the antigen being presented would be independent of disease and as such could target any disease that presents antigens in a specific manner. Thus, the working examples directed to anti-tumor responses provide sufficient guidance to one of skill in the art interested in generating an anti-viral response. Accordingly, the specification provides sufficient guidance to practice the claimed invention without undue experimentation.

The Office Action argues that "[a]dministering DNA encoding gp120 or gp160 to an individual does not elicit an anti-HIV immune response that destroys HIV infected cells as discussed in the art at the time of filing." The art discussed on the Office Action does not support this conclusion, however. Instead, the art discussed in the Office Action generally shows that "attempts to develop a vaccine against HIV have been unsuccessful." Yet, a vaccine can destroy HIV infected cells, which could be useful as a therapy either alone or in combination with other treatments, and still be unsuccessful as a vaccine. For example, "Veljkovic taught HIV can escape from immune control by HIV-specific CTL recognizing a single epitope undergoes viral mutation and is favored when the CTL response is against one HIV epitope (pg 1857, col. 1, last sentence of the first full paragraph)." Office Action at 4-5. Thus, Veljkovic shows that HIV cells that do not undergo mutation cannot escape the CTL response. Accordingly, Veljkovic supports the conclusion that HIV infected cells can be destroyed.

Applicants note that new claim 113 does not require the destroying of virally-infected cells, and new claim 114 is not directed to an anti-viral response. Accordingly, these claims are believed to avoid the rejection, if in view of the examiner's rationale.

In addition, Applicants note that claims 41, 56, 92, and 108 have been canceled.

B. Non-Enablement Of HIV Treatment "Using DNA Encoding Gp120 Or Gp160" Does Not Render The Claimed Invention Non-Enabled

The Office Action attacks the enablement of the claimed invention by arguing that the specification fails to enable treatment of HIV "using DNA encoding gp120 or gp160." This contention over looks the fact that claim 29 and its dependent claims are drawn to a method of treatment that elicits an "an anti-tumor or anti-viral immune response in said host that destroys neoplastic or virally infected cells."

Even assuming, *arguendo*, the non-enabled quality of a HIV treatment that entails "using DNA encoding gp120 or gp160," the claimed invention itself still would be enabled. "A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable." MPEP § 2164.08(b). Here, the specification discloses actual examples demonstrating the efficacy of the claimed invention, and the Office Action limits its discussion to treatment of HIV. Accordingly, the specification enables the claimed invention.

The pending claims were previously rejected as lacking enablement, and the Board of Patent Appeals and Interferences reversed the rejection noting that "the evidence relied upon by the examiner fails to demonstrate that the claimed invention is non-enabled throughout its entire scope." Board Decision of January 29, 2003 at 6 (emphasis added). Like the previous rejection, the present rejection fails to demonstrate the claimed invention is non-enabled throughout its entire scope. Accordingly, a *prima facie* case of non-enablement has not been established.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

II. Claim Rejections – 35 U.S.C. § 102

The Office Action makes the following rejections under 35 U.S.C. § 102:

(a) Claims 29, 68, 69, 72-74, 82, 84, 85, 95 and 100 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Webster, Vaccine 12(16):1495-1498 (1994) as supported by Robinson (Seminars in Immunology, 1997, Vol. 9, pg 271-283), Kuby (Immunology, 1992, W.H. Freeman and Company, New York, pg 208) and Peachman (Methods, 2003, Vol. 31, pg 232-242);

(b) Claims 29, 68, 69, 72-74, 82, 84, 85,92, 95 and 100 stand rejected under 35 U.S.C. 102(a) as allegedly anticipated by Haynes (AIDS research and human retroviruses, 1994, Vol. 10, Supplement 2, pg S43-45) or Haynes (Vaccine, 1994, Cold Spring Harbor, Modern approaches to new vaccines including prevention of AIDS, pg 65-70), as supported by Robinson (Seminars in Immunology, 1997, Vol. 9, pg 271-283), Kuby (Immunology, 1.992, W.H. Freeman and Company, New York, pg 208) and Peachman (Methods, 2003, Vol. 31, pg 232-242);

(c) Claims 29, 68, 69, 72-74,82, 84, 85,92, 95 and 100 stand rejected under 35 U.S.C. 102(b) as allegedly "anticipated by the abstract presented by Haynes at the 11th annual meeting on modern approaches to new vaccines in September 1993 as supported by Robinson (Seminars in Immunology, 1997, Vol. 9, pg 271-283), Kuby (Immunology, 1992, W.H. Freeman and Company, New York, pg 208) and Peachman (Methods, 2003, Vol. 31, pg 232-242)";

(d) Claims 29, 68, 69, 72-74, 82, 84, 85,95 and 100 stand rejected under 35 U.S.C. 102(a) as allegedly anticipated by Lai (DNA and cell biology, July 1995, Vol. 14, No. 7, pg 643-651) as supported by Robinson (Seminars in Immunology, 1997,

Vol. 9, pg 271 -283), Kuby (Immunology, 1992, W.H. Freeman and Company, New York, pg 208) and Peachman (Methods, 2003, Vol. 31, pg 232-242);

(e) Claims 29, 68, 69, 71, 72, 74, 82, 84,98, and 100 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Hui (J. immunological Methods, May 16, 1994, Vol. 171, pg 147-155) as supported by Robinson (Seminars in Immunology, 1997, Vol. 9, pg 271-283) and Kuby (Immunology, 1992, W.H. Freeman and Company, New York, P9 208); and

(f) Claims 29-32, 34,40,41,44-47,49,55, 56,59-61, 63,68-85,91 and 92 stand rejected under 35 U.S.C. 102(e) as allegedly anticipated by Weiner (US Patent 5,593,972) of record as supported by Peachman (Methods, 2003, Vol. 31, pg 232-242).

For each ground of rejection (a)-(f), the Office Action states that "[t]he board's belief that 'direct injection' and 'particulate bombardment' are mutually exclusive (paragraph bridging pg 9-10 of the decision by the board 1-29-03) is in error." Office Action at 8, 11, 14, 17, and 20-21. Applicants respectfully traverse this ground of rejection.

"Direct injection" does not encompass "particulate bombardment," such as through the use of a gene gun, as discussed in Applicants' appeal brief filed February 15, 2000. The Board agreed with Applicants and stated as follows:

> We also note, as do appellants (Brief, page 7), that the examiner has incorrectly interpreted the claim limitation of "direct injection," as set forth in claim 29, "as encompassing both direct injection using a gene-gun as well as direct injection without use of a gene-gun." Answer, page 9 and 10. ***We wish to emphasize that not only do appellants' claims distinguish between "direct injection" see e.g., claim 29 and inoculating using a biolistic device see e.g, claim 15, but appellants' specification distinguishes between the two terms.*** See specification, page 15, "[a] mammalian host may be immunized . . . by a biolistic . . . delivery procedure.. .. In another embodiment of the present invention a mammalian host is immunized .. . by direct injection, including but not limited to subcutaneous injection, epidermal injection, dermal injection, lymphatic injection and intra

> venous injection." ***Accordingly, the examiner has incorrectly construed appellants' claimed invention.***

Board decision dated January 29, 2003 at 9-10 (emphasis added). In other words, the Board already has considered and flatly rejected the Office Action's current interpretation of "direct injection," which encompasses the use of a gene gun. Since the case was not remanded for consideration of this issue, no jurisdiction resides in the examiner to reconsider the aspect in question of the Board's decision. *See* 37 C.F.R. § 41.50.

It is improper to ignore the Board's holding simply because the Examiner disagrees, especially since the disagreement is based on evidence that was before the Board, namely, the specification itself. Such an approach would undermine the entire appellate process.

Because each of the references used to make rejections (a)-(f) rely on the use of a gene gun rather than "direct injection," the references fail to teach each and every element of the claimed invention. Accordingly, the references cannot anticipate the claims.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

Should the examiner feel that any other issue requires further consideration, she is invited to contact the undersigned directly. Also, the Commissioner is authorized to charge any additional fees that may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions are needed for timely acceptance of submitted papers, Applicants petition for such extension under 37 CFR § 1.136 and authorize payment of any fees to Account No. 19-0741.

Respectfully submitted,

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